



## **Rx: Health Care FYI #15**

**Subject:** *Extending The Shelf Life of Prescription Drugs*

**From:** *Rep. Tim Murphy (PA-18)*

**The problem:** Often the expiration dates of prescription and over-the-counter drugs do not accurately reflect the true shelf life, resulting in billions of dollars wasted annually on discarded drugs that are potentially still potent and safe beyond their labeled expiration dates.

- Since 1979, the FDA has required pharmaceutical companies to define their own expiration date for each drug marketed in the U.S.
- This expiration date specifies only the date the manufacturer guarantees the full potency and safety of the drug; it does not identify how long the drug is actually effective.
- In addition, 17 states require that pharmacists assign a “beyond-use” date to medications dispensed in a container that is different from the original manufacturers packaging. This “beyond use” date cannot exceed the manufacturer’s expiration date. However, it is usually shorter than the actual expiration date.<sup>1</sup>
- While it is not known how much of the \$179 billion spent annually in the U.S. on medicines<sup>2</sup> goes to replace expired ones, a 2000 Wall Street Journal poll of 1,000 respondents found that 70% probably would not take a prescription drug after its expiration date and 72% would not take an over-the-counter remedy after the expiration date.<sup>3</sup>

### **The federal government’s role:**

- The FDA administers the Shelf Life Extension Program (SLEP) for the U.S. military. SLEP is an internal, accelerated stability test program for drug products to determine the safety and effectiveness of prescription and over-the-counter “stockpiled” drugs purchased in bulk by the military. Every batch of a to-be-stockpiled drug product purchased by the military is tested and tracked in order to extend the expiration date for that batch.

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<sup>1</sup> American Medical Association. Report 1 of the Council on Scientific Affairs. Pharmaceutical Expiration Dates. June 2001.

<sup>2</sup> Heffler, Stephen. U.S. Health Spending Projections For 2004–2014. Office of the Actuary, Centers for Medicare and Medicaid Services. Health Affairs. February 2005.

<sup>3</sup> Cohen, Laurie. Drugs Frequently Potent Past Expiration. The Wall Street Journal. March 29, 2000.

- In 1986, SLEP tested over 100 prescription and over-the-counter drugs in the first year of the program and found that over 90% were safe and effective far past their original expiration date, in some instances for up to 15 years.<sup>3</sup>
- As of March 2000, SLEP has evaluated and tested 312 drug products and many maintained their stability, safety and potency up to as much as an additional 107 months past their expiration dates.<sup>4</sup>
- The U.S. military spent \$3.9 million on stability testing on expired drugs and saved \$263.4 million on drug expenses from 1993 through 1998.<sup>3</sup>

#### **Recommendations:**

- Support studies to determine whether lengthening of expiration dates of prescription and over-the-counter drugs will provide clinical and/or economic benefits and report possible risks for patients.
- Encourage states to evaluate the accuracy of “beyond use” dates on repackaged pharmaceuticals.
- HHS could convene a working group of scientific, medical and pharmaceutical experts to evaluate the FDA’s current expiration date regulations.
- Create a pilot program/demonstration project based on the U.S. Department of Defense’s SLEP program in the consumer marketplace to determine if the savings gained by the military can be applied to general health care spending.

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<sup>4</sup> Letter to Jeffrey E. Shuren, MD, JD, Food and Drug Administration. March 28, 2001.